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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/998,716	11/30/2001	Alex J. Harvey	AVI 019	7210

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Judy Jarecki-Black, Ph.D., J.D.
AviGenics, Inc.
111 Riverbend Road
Athens, GA 30605

EXAMINER

WILSON, MICHAEL C

ART UNIT

PAPER NUMBER

1632

DATE MAILED: 05/22/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/998,716

Applicant(s)

HARVEY ET AL.

Examiner

Michael C. Wilson

Art Unit

1632

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is FINAL. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-50 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 1-50 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☒ Other: See Continuation Sheet.

Continuation of Attachment(s) 6). Other: Raw Seq. Error Report and Notice to Comply.

DETAILED ACTION

Claims 1-50 are pending and under consideration.

Specification

This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 CFR 1.821 through 1.825 for the reason(s) set forth on the attached Notice To Comply With Requirements For Patent Applications Containing Nucleotide Sequence And/Or Amino Acid Sequence Disclosures. **The computer readable form (CRF) has errors. See attached Raw Sequence Listing Error Report.** Applicants must file a "Sequence Listing" accompanied by directions to enter the listing into the specification as an amendment. Applicant also must provide statements regarding sameness and new matter with regards to the CRF and the "Sequence Listing." Applicant is requested to return a copy of the attached Notice to Comply with the reply. Failure to fully comply with the sequence rules in response to the instant office action will be considered non-responsive.

The blank on pg 22, line 19, needs filled in.

The status of the patent application on pg 27, line 23, will need to be updated upon being allowed or abandoned.

Drawings

The drawings are objected to because Fig 4 is four pages long. A proposed drawing correction or corrected drawings are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance. The four pages should be labeled Fig. 4A, Fig. 4B, Fig. 4C and Fig.4D, respectively. The description of Fig. 4 on pg 6, line 22, should be changed to Fig. 4A-4D.

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-37, drawn to a nucleic acid comprising an avian ovomucoid gene expression control region comprising SEQ ID NO:26 or a degenerate variant thereof, a vector comprising an avian ovomucoid gene expression control region operably linked to a nucleic acid encoding a protein, a method of expressing a heterologous protein in a host cell using DNA comprising an avian ovomucoid gene expression control region and a cell transformed with said vector, classified in class 536, subclass 23.1.
- II. Claims 38-47, drawn to a transgenic avian having a heterologous nucleic acid sequence comprising an avian ovomucoid gene expression control region, classified in class 800, subclass 19.

- III. Claims 48-50, drawn to a nucleic acid sequence having a codon complement optimized for protein expression in an avian, classified in class 536, subclass 23.1.

The inventions are distinct, each from the other because of the following reasons:

Groups I and II are patentably distinct because the nucleic acid of Group I can be used to express proteins in any cell in vitro, while the transgenic avian of Group II can be used as a model of disease. The protocols and reagents required for the nucleic acid of Group I and the transgenic avian of Group II are materially distinct and separate. The nucleic acid does not require the transgenic avian and the transgenic avian does not require the nucleic acid.

Groups I and III are patentably distinct because the nucleic acid of Group I controls expression of coding sequences while the nucleic acid of Group II "codon complement" which does have a disclosed function. Therefore, the nucleic acid comprising an avian ovomucoid expression control region and the "codon complement" do not have the same structure or function. The search required for Group I is mutually exclusive from the search required for Group II and would be undue to search together. The nucleic acid of Group I does not require the nucleic acid of Group II and vice versa.

Groups II and III are patentably distinct because the transgenic avian of Group II requires an avian ovomucoid expression control region while the nucleic acid of Group III requires a "codon complement". The protocols and reagents required for the transgenic avian of Group II are materially distinct and separate from the nucleic acids

of Group III. The nucleic acid does not require the transgenic avian and the transgenic avian does not require the nucleic acid.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Inquiry concerning this communication or earlier communications from the examiner should be directed to Michael C. Wilson who can normally be reached on Monday through Friday from 9:00 am to 5:30 pm at (703) 305-0120.

Questions of formal matters can be directed to the patent analyst, Dianiece Jacobs, who can normally be reached on Monday through Friday from 9:00 am to 5:30 pm at (703) 305-3388.

Questions of a general nature relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-1235.

If attempts to reach the examiner, patent analyst or Group receptionist are unsuccessful, the examiner's supervisor, Deborah Reynolds, can be reached on (703) 305-4051.

The official fax number for this Group is (703) 308-4242.

Michael C. Wilson



MICHAEL WILSON
PRIMARY EXAMINER